CMR

09-1022

*JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

EDDIE JAMES WESTBROOKS, III, individually, and as the Administrator of the estate of EDDIE JAMES WESTBROOKS, JR.

(b) County of Residence of First Listed Plaintiff Muscogee
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Aylstock, Witkin, Kreis & Overholtz, PLLC; 803 N. Palafox St., Pensacola, FL 32501; (850) 916-7450 - Neil D. Overholtz, Esq.

DEFENDANTS

SmithKline Beecham Corporation d/b/a GlaxoSmithKline and GlaxoSmithKline, PLC

County of Residence of First Listed Defendant Philadelphia
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN
(Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**): 28 U.S.C.A. § 1332

Brief description of cause: Diverse Citizenship

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Cynthia M. Rufe DOCKET NUMBER 1871, JPMDL

DATE 03/06/2009

SIGNATURE OF ATTORNEY OF RECORD

CMR MAR 9 2009

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

CMR

09-1022

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to the appropriate calendar.

Address of Plaintiff: 207 32nd AVENUE COLUMBUS, GA 31903

Address of Defendant: 1 FRANKLIN PLAZA 200 N. 16th STREET PHILADELPHIA, PA 19102

Place of Accident, Incident or Transaction: COLUMBUS, GA 31907
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☐

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: MDL 1871 Judge Cynthia Rufe Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☐

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☐

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☐

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*
1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
(Please specify)

B. *Diversity Jurisdiction Cases:*
1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION
(Check appropriate Category)

MAR 0 2009

I, R. JASON RICHARDS, ESQ., counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 3/9/09 Attorney-at-Law 0018207 (Florida) Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 3/9/09 Attorney-at-Law 0018207 (Florida) Attorney I.D.#

CIV. 609 (6/08)

APPENDIX I

CMR

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

EDDIE JAMES WESTBROOKS, III, ET AL. : CIVIL ACTION
v. :
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE, PLC : NO. 09-1022

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

MAR 9 2009

3/9/09	[signature]	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
850-916-7430	850-916-7449	cjasonrichards@awkolaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

$350 CMR

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

EDDIE JAMES WESTBROOKS, III, individually, and as the Administrator of the Estate of EDDIE JAMES WESTBROOKS, JR.

vs.

SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE

Defendant.

09-1022

07-MD-01871-CMR

Case No.:

COMPLAINT
(Jury Demand Requested)

FILED
MAR 9 2009
MICHAEL E. KUNZ, Clerk
By_____Dep. Clerk

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, EDDIE JAMES WESTBROOKS III, individually, and as the Administrator of the Estate of EDDIE JAMES WESTBROOKS, JR., Deceased, by and through her below-listed attorneys, alleges upon information and belief the following:

STATEMENT OF FACTS

1. This is an action to recover damages for the personal injuries and wrongful death sustained by the Decedent, EDDIE JAMES WESTBROOKS, JR. (hereinafter referred to as "Decedent"), as the direct and proximate result of the wrongful conduct of the Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE (hereinafter referred to as "Defendant" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia (rosiglitazone).

MAR 9 2009

JURISDICTION AND VENUE

2. Jurisdiction is proper in this Court pursuant to 28 U.S.C.A. § 1332. All parties to this action are of diverse citizenship. The amount in controversy exceeds $75,000 exclusive of interests and costs.

3. Venue is proper in this Court pursuant to 28 U.S.C.A. § 1391 because a substantial portion of the conduct alleged occurred within the Eastern District of Pennsylvania. In addition, the Eastern District of Pennsylvania is where the Defendant resides.

PLAINTIFF'S ALLEGATIONS

4. Plaintiff files this action against the named Defendant for personal injuries and the wrongful death of Decedent which occurred as a result of the ingestion of the defective and dangerous pharmaceutical antidiabetic drug Avandia® which was researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, supplied, packaged and/or sold by Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline as more fully detailed below.

5. Plaintiff is a citizen and resident of the State of Georgia.

6. At the time of his death, Decedent was a resident and citizen of the State of Georgia.

7. Decedent was diagnosed with Type II diabetes.

8. Decedent was prescribed and ingested Avandia (rosiglitazone), a pharmaceutical product designed and manufactured by Defendant, from approximately December 2005 to December 2006.

9. Decedent suffered severe injury to his heart and died, which was caused by Defendant's Avandia.

10. The Plaintiff named herein has filed this lawsuit within the applicable statute of limitations period. The Plaintiff named herein acted with diligence in attempting to discover any injury caused by Decedent's ingestion of Avandia.

11. But for Defendant's actions, Plaintiff and Decedent did not discover, were prevented from discovering and/or could not have discovered Decedent's injuries earlier because of the Defendant's fraudulent misrepresentations, concealment of the facts and/or the nature of the injuries involved, as more specifically alleged herein.

DEFENDANT

12. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a Pennsylvania corporation, with its principal place of business located at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania. SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a wholly-owned subsidiary of GlaxoSmithKline, PLC, and also conducts pharmaceutical research and development in the United States under the corporate fictitious name GlaxoSmithKline. SmithKline Beecham Corporation d/b/a GlaxoSmithKline, on information and belief, at all times relevant, manufactured, advertised, labeled, marketed, promoted, sold, and distributed Avandia (rosiglitazone) in the United States, including the State of Georgia.

13. At all times material to this lawsuit, Defendant was engaged in the business of, or was a successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising,

distributing and/or selling the prescription drug product Avandia, Avandamet and Avandaryl (hereinafter referred to collectively as "Avandia" or "rosiglitazone") as an antidiabetic medication to the general public including Decedent.

14. At all times material to this lawsuit, Defendant was authorized to do business within the State of Pennsylvania and derived substantial revenues from products designed and manufactured in Pennsylvania and within this district.

INTRODUCTION

15. Defendant manufactured, promoted, distributed, labeled, and marketed rosiglitazone under the trade name(s) of Avandia® Tablets, Avandamet® Tablets, and Avandaryl® Tablets.

16. Rosiglitazone is a member of a class of drugs known as Thiazolidinediones (TZDs).

17. Avandia® was first approved for use in the United States in 1999 for the use in treatment of Type II diabetes mellitus, also known as non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes.

18. In 2002, Avandamet®, a single pill combination of Avandia® and metformin, was approved in the United States for use in treatment of Type II diabetes mellitus.

19. In 2005, Avandaryl®, a single pill combination of Avandia® and Amaryl®, likewise was approved in the United States for use in treatment of Type II diabetes mellitus.

20. Most people with diabetes have health problems -- or risk factors -- that increase the risk for heart disease and stroke. More than 65% of people with diabetes die from heart disease or stroke.

21. Cardiovascular disease (CVD) is the main cause of death in these patients. Thus, it is important that an antidiabetic agent reduce the risk of cardiovascular injury.

22. During the past decade, numerous drugs have been introduced for the treatment of Type II diabetes that, used in monotherapy or in combination therapy, are supposed to better control the disease in patients and reduce the health complications often associated with diabetes, such as heart attacks, strokes, heart injury and other cardiovascular complications.

23. Thiazolidinediones (TZDs) are a novel class of insulin-sensitizing antidiabetic agents. In the USA and Canada, two TZDs are indicated for use in Type II diabetes mellitus, rosiglitazone and pioglitazone. A third, troglitazone (Rezulin) has been removed from the market because of an association with significant hepatotoxicity.

24. The antidiabetic actions of TZDs are likely mediated by their interaction with the nuclear receptor peroxisome proliferator-activated receptor-gamma (PPARγ).

25. Decedent took, ingested, used or otherwise was exposed to the drug rosiglitazone ("Avandia").

26. The Avandia which Decedent was prescribed and ingested, and which caused Decedent to suffer serious cardiovascular injuries and death, was defective and unreasonably dangerous in that Avandia: was not reasonably safe for its intended use as an antidiabetic drug; subjected Decedent to risks which exceeded the benefits of Avandia, if any; was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; was more dangerous than other risks associated with diabetes and other anti-diabetic medications; and was otherwise defective and unreasonably dangerous as set forth herein.

27. The defective and unreasonably dangerous Avandia caused Decedent to suffer serious cardiovascular injuries and death.

28. Before Decedent was prescribed and ingested Avandia which caused his the injuries as alleged herein, Defendant knew or should have known that the Avandia had been related to and associated with these serious and life threatening side effects. Defendant had an obligation under the law to disclose, adequately, the association between Avandia and congestive heart failure, heart attack, fluid retention, fluid overload, and other serious cardiovascular injuries. Due to Defendant's failure to adequately warn Decedent, Decedent's doctors prescribing the Avandia and others of the known risks of suffering congestive heart failure, heart attack, fluid retention, fluid overload, and other serious cardiovascular injuries, Decedent's physicians were unable to inform Decedent of the true risks associated with the ingestion of the Avandia including the injuries suffered by Decedent as described herein. These side effects were known or should have been known to Defendant at the time that it marketed Avandia to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drug. Defendant did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did Defendant perform adequate post-marketing surveillance and monitoring which would have otherwise prevented Decedent's injuries. Rather, Defendant through its marketing and promotional campaigns downplayed and/or obfuscated evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

A. DEFENDANT KNEW OR SHOULD HAVE KNOWN THAT INGESTING AVANDIA INCREASES THE RISK OF MYOCARDIAL INFARCTION, STROKE AND OTHER SERIOUS HEART INJURIES AND DEATH

29. Defendant knew as early as 1999 that Avandia was unreasonably dangerous and could also cause heart attacks, strokes, serious cardiovascular injuries and death.

30. In 1999, Dr. John B. Buse (the current president-elect of the American Diabetes Association), a diabetes expert and head of endocrinology at the University of North Carolina, Chapel Hill, raised concerns about Avandia and heart problems, including the risk of heart attack, cardiovascular injury and death.

31. Defendant attempted to silence Dr. Buse and further conceal the true nature of Avandia risks by threatening Dr. Buse with a $4 Million lawsuit and by characterizing him as a liar.[1]

32. In response to Defendant's pressure, Dr. Buse sent a three-page letter to Dr. Tadataka Yamada, Defendant's Chairman of Research and Development. In the letter, Dr. Buse wrote, "I may disagree with GSK's interpretation of that data...I am not for sale ... Please call off the dogs. I cannot remain civilized much longer under this kind of heat." As a result of Defendant's threats, Dr. Buse eventually signed a clarifying statement with the company.

33. On March 15, 2000, Dr. Buse wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia:

> I would like you to know exactly what my concerns are regarding rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program (whether the number we accept as the truth is the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed) one would expect an increase in cardiovascular events....Based on studies with statins and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks[2].

---

[1] John Buse, M.D. Congressional Hearing Transcript (June 6, 2007).
[2] Letter from Dr. Buse to FDA (March 15, 2000).

34. Dr. Buse was not the only person to alert Defendant to the increased risk of heart attack, serious cardiovascular injury and death associated with Avandia. Shortly after Dr. Buse raised concerns related to increased risk of cardiovascular injuries associated with Avandia, Public Citizen filed a petition, on March 7, 2000, seeking immediate class labeling changes for all marketed TZDs, including rosiglitazone.[3]

35. In an independent investigation of the TZDs, Public Citizen, after studying reviews by FDA Medical Officers, Statisticians, and Pharmacologists, transcripts of FDA advisory committee meetings, and scientific literature on trolitazone, rosiglitazone, and pioglitazone, argued that information associating rosiglitazone to heart attacks and serious cardiovascular injuries "was never included in the label, or seriously understated."[4]

36. Public Citizen cited studies submitted to the FDA for approval that evidenced lack of efficacy and increase in cardiovascular risks.

37. Public Citizen argued that nowhere in the product insert was there any mention of myocardial infarction even where the increased risk of myocardial infarctions was found in Defendant's own studies.

38. Public Citizen pointed to several studies, many of which were studies conducted by Defendant. The conclusion reached by Public Citizen was that rosiglitazone was not as effective as alleged and the ingestion of rosiglitazone increased the risk of myocardial infarction, death and other serious cardiovascular injuries.[5]

39. This is obviously a major concern since diabetics are already susceptible to an increased risk of cardiovascular injury.

---

[3] Public Citizen's Petition to the FDA requesting that it immediately require labeling for diabetes drugs troglitazone (Rezulin), rosiglitazone (Avandia) and pioglitazone (Actos) (HRG Publication #1514) (March 7, 2000)
[4] *Id.* at 1
[5] *Id.* at 6

40. In addition to the concerns raised by Dr. Buse and Public Citizen, there have also been at least three meta-analyses conducted each of which found that Avandia increases the risk of cardiovascular-related injury, including but not limited to myocardial infarction and death.

41. The first analysis was performed by Defendant and was handed over to the FDA in August of 2006. The meta-analysis consisted of 42 separate double-blinded, randomized, controlled clinical trials to assess the efficacy of rosiglitazone for treatment of Type II diabetes compared to either placebo or other antidiabetic therapies in patients with Type II diabetes. The combined studies included 8,604 patients on rosiglitazone and 5,633 patients randomized to a variety of alternative therapeutic regimens, including placebo.

42. Defendant's own meta-analysis found an overall incidence of myocardial ischemia in rosiglitazone-treated subjects. The risk equated to more than a 30% excess risk of myocardial ischemic events in rosiglitazone-treated patients.

43. A second meta-analysis conducted by Dr. Steven Nissen and Kathy Wolski titled *Effects of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes* was published on May 21, 2007, in the New England Journal of Medicine (NEJM).

44. Nissen and Wolski reviewed data available to them through published literature, the FDA website, and GlaxoSmithKline's clinical-trials registry. The analysis included a review of 42 clinical trials involving nearly 28,000 patients.

45. Nissen and Wolski concluded "[r]osiglitazone was associated with a significant increase in the risk of myocardial infarction and with an increase in the risk of death from cardiovascular causes that had borderline significance."[6]

---

[6] Nissen SE and Wolski K., *Effects of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes, N Engl J Med*; 356, May 21, 2007.

46. Hence, it was found that patients suffering from Type II diabetes mellitus have a higher risk of experiencing a heart attack and cardiovascular injuries than non-diabetic patients. But a diabetic taking Avandia has a much greater risk of suffering a heart attack or serious cardiovascular event – an estimated 43% increase or greater risk when compared with other diabetes drugs or placebos.

47. On July 30, 2007, the FDA presented its results of the FDA meta-analysis. Similar to Defendant and Nissen/Wolski's findings, the FDA likewise found an increased risk of heart attack, cardiovascular death and other serious adverse events and ultimately recommended that a boxed warning be placed on the Avandia label.

48. Thus, while Defendant's rosiglitazone-containing drugs are marketed and sold by Defendant as antidiabetic agents that reduce a diabetic patient's risk of cardiovascular injuries, studies conducted by Defendant showed that rosiglitazone actually increases those risks by 43% according to the Nissen/Wolski meta-analysis and by 31% according to Defendant's own meta-analysis.

49. Yet, even with this information available to it, Defendant failed to warn consumers and the medical community about the increased risk of heart injuries, including but not limited to, heart attacks, strokes, cardiovascular injury and other serious injuries, including death, from using Avandia.

50. Following the May 21, 2007 NEJM publication of the Nissen/Wolski meta-analysis, the FDA issued a safety alert for Avandia and advised patients who take it to consult their doctors.

51. Dr. David Graham, testifying on behalf of the FDA at the July 30, 2007, FDA Avandia safety hearing, called for withdrawing Avandia from the market and estimated that its

toxic effects on the heart had caused up to 205,000 heart attacks and strokes, some fatal, from 1999 to 2006. For every month that Avandia is sold, Dr. Graham said, 1,600 to 2,200 patients will suffer more of those problems.

52. The FDA provided testimony that Avandia offers no unique benefits compared to other drugs in battling diabetes, but that all indications point to increased risks of heart attack and sudden death.

53. The panel of advisers to the Food and Drug Administration voted 20-to-3 that Avandia increases the risks of heart attacks.

54. On or about November 14, 2007, the FDA announced that a boxed warning would be added to the Avandia label related to the increased risk of suffering myocardial infarction (heart attack).

B. DEFENDANT KNEW OR SHOULD HAVE KNOWN THAT INGESTING AVANDIA INCREASES THE RISK OF CONGESTIVE HEART FAILURE

55. As early as 2002, there were serious and substantial reports of Avandia-related heart failure that resulted in hospitalizations. At the time, FDA scientists recommended the drug's label be revised to reflect the possible risk of heart failure as revealed by post-marketing reports. In 2002, the FDA recommended the Defendant mention post-marketing cases of heart failure.[7]

56. Despite this 2002 recommendation to mention post-marketing cases of heart failure the labeling at the time Decedent began ingesting Avandia was wholly inadequate to apprise Decedent of the true risks associated with Defendant's Avandia. It wasn't until five years later that the labeling was adequately updated with a heightened black box heart failure warning.

[7] Internal Food and Drug Administration Memo (2002)

57. A clinical trial sponsored by the Defendant revealed that Avandia users were more than twice as likely to develop congestive heart failure than patients using other diabetes drugs.

58. Researchers at Wake Forest University conducted an analysis of four long-term studies involving more than 14,000 patients and the study also concluded that Avandia doubles the risk of heart failure and increases the risk of heart attack by more than 40%.

59. Dr. Sonal Singh, co-author of the Wake Forest University study has stated that risk of developing heart failure due to Avandia is 1 in 30 and the risk of having a heart attack is 1 in 220.

60. Avandia has been the subject of controversy since May when the *New England Journal of Medicine* published a meta-analysis of 44 studies that linked the drug to an increased risk of heart attacks.

61. Following the May 21, 2007 NEJM publication of the Nissen/Wolski meta-analysis, the FDA issued a safety alert for Avandia and advised patients who take it to consult their doctors.

62. At a congressional hearing held on June 6, 2007, the FDA indicated that a black box warning should be added to rosiglitazone (Avandia), for increased risk of heart failure.

63. The black box warning was added to the label in August of 2007, providing a heightened warning regarding the association of Avandia use and congestive heart failure.

C. AVANDIA IS NOT AS EFFECTIVE AS DEFENDANT PROMOTE IT TO BE.

64. Defendant has promoted and marketed Avandia as being more effective than older antidiabetic agents and other TZDs; however, there is no direct evidence that lowering glucose or HbA1c levels with rosiglitazone reduces the risks of microvascular or macrovascular

disease or mortality in patients with Type II diabetes. There is some evidence that other oral hypoglycemics do succeed in doing so.[8]

65. Moreover, researchers recently concluded that older antidiabetic agents are as effective or superior to rosiglitazone.[9]

GENERAL ALLEGATIONS

66. Avandia was supplied, compounded, packaged, re-packaged, marketed, promoted, advertised, warranted, distributed and/or sold by Defendant, as effective and safe antidiabetic medication. Defendant sold and distributed Avandia in the State of Georgia and into the stream of commerce knowing that it would enter the State of Georgia and be used therein.

67. Defendant researched, formulated, made, created, developed, manufactured, assembled, designed, sterilized, tested, evaluated, licensed, labeled, supplied, compounded, packaged, re-packaged, marketed, promoted, advertised, warranted, distributed and/or sold Avandia in the State of Georgia. These same Defendant had assisted in and had control over the design, assembly, packaging, labeling, marketing, advertising, manufacturing and sale of Avandia.

68. Defendant knew or should have known that Avandia, when used alone or in combination, created significant risks of serious injuries or disorders, heart attack, stroke, congestive heart failure, and severe injury to the heart which could lead to cardiac arrest and death. Defendant failed to make proper, reasonable or adequate warning to the public about these risks associated with the use of Avandia.

---

[8] UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes: UKPDS 33. The Lancet 1998; 352:837-853.

[9] *See* Bolen, et al. *Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus*. Annals of Internal Medicine. (Sept. 2007)

69. At all times material hereto, though Defendant knew or should have known that dangerous risks were associated with the use of Avandia, Defendant proceeded to or permitted Avandia to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, supplied, packaged and/or sold without adequate warnings of the serious side effects and dangerous risks.

70. Both during the marketing and sale of Avandia and during the initial submission of the Avandia NDA, Defendant did not adequately report to the FDA, the public, and Decedent's physicians information in its possession which related directly the risk of developing heart attack, stroke, congestive heart failure, and severe injury to the heart which could lead to cardiac arrest and death. The public, the FDA, the medical community, Decedent's physicians and Decedent were misled by these actions and omissions, resulting in Decedent having received no warnings or inadequate warnings regarding the true risks associated with ingesting Avandia.

71. Defendant failed to conduct sufficient and adequate pre-marketing research and testing to properly determine the risks and severity of serious side effects including the serious and substantial risk of developing heart attack, stroke, congestive heart failure, and severe injury to the heart which could lead to cardiac arrest and death caused by the ingestion of Avandia.

72. Defendant failed to conduct sufficient and adequate post-marketing surveillance as to the ingestion of Avandia and resultant adverse events and side effects to both properly determine and quantify the risks and severity of serious side effects and take reasonable and necessary remedial action to protect the public, including Decedent, from injuries and death suffered by Avandia users.

73. Defendant failed to adequately warn Decedent directly or by and through his prescribing physician of the hazards of the use of Avandia and concealed this knowledge from

Decedent and others. Decedent's prescribing physicians did not have available to them the body of knowledge that an adequate warning from Defendant would have communicated to Decedent's prescribing physicians. As a result of this failure to warn, Decedent was caused to suffer the personal injuries as alleged and damages hereinafter set forth.

74. Decedent was prescribed and took Avandia for diabetes treatment, and suffered injury thereby in the State of Georgia.

75. Defendant undertook a course of action and marketing strategy which included advertising and promotional campaigns to aggressively promote and sell Avandia.

76. The product warning in effect during the time Avandia was prescribed was non-existent or inadequate as to the need to alert prescribing physicians and consumer patients of the actual adverse health risks associated with Avandia, which risks were then known or should have been known to Defendant. Potential users were not informed about the products and the serious health effects, including death, which Defendant knew or should have known could result from the use of Avandia.

77. Defendant, through its misrepresentations and omissions, created the impression and conveyed to Decedent and others on whom Decedent would rely, that the use of Avandia was safe and had fewer adverse health and side effects than were actually associated with Avandia.

78. Defendant undertook a promotional campaign that included the funding of and/or placement of numerous articles in scientific, medical and general interest magazines extolling the virtues of Avandia in order to induce widespread use of the products.

79. Defendant downplayed and understated the health hazards and risks associated with Avandia.

80. Defendant failed to reveal relevant information to doctors and potential Avandia users including Decedent and his physicians regarding the safety of Avandia.

81. Defendant, through its product inserts and other documents, misrepresented a number of facts regarding Avandia, including the following:

a. The presence of adequate testing of Avandia;

b. Avandia's true efficacy including, but not limited to, the severity, frequency and discomfort of side effects and adverse health effects caused by the drugs; and,

c. The relative risks associated with Avandia including the prevalence of heart attack, stroke, congestive heart failure, and severe injury to the heart which could lead to cardiac arrest and death.

82. After learning of the extreme dangers associated with Avandia, Defendant did not adequately or appropriately provide information about Avandia or other relevant information to physicians in the United States, including Decedent's physicians.

83. At all times relevant hereto, Defendant's labeling on Avandia was inadequate to alert Decedent, prescribing physicians and others on whom it knew or should have known Decedent would rely of heart attacks, strokes, congestive heart failure, severe heart injury and death and other dangers and risks associated with Avandia usage. As a result, physicians have over-prescribed Avandia to patients who were under-informed regarding the risks described herein associated with Avandia.

84. Defendant, having undertaken the manufacture, sale, marketing, distribution and promotion of Avandia described herein, owed a duty to provide Decedent, physicians and others on whom Decedent would and did rely, accurate and complete information regarding Avandia.

85. Defendant indicated to Decedent, Decedent's physicians and others on whom Decedent relied that Avandia was safe and effective, that the benefits of taking Avandia

outweighed any of its risks and provided inaccurate safety and effectiveness information regarding its products including, but not limited to, the propensity to cause serious physical harm. The continuous and ongoing course of action started as early as 1999, if not earlier, and continued through repeated acts and non-disclosure every year since then in the State of Pennsylvania, throughout the United States, and elsewhere.

86. Defendant's fraudulent misrepresentations took the form of, among other forms, express and implied statements, publicly-disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about Avandia, failure to disclose important safety and injury information regarding Avandia while having a duty to disclose to Decedent and others such information, and elaborate marketing, promotional, and advertising activities.

87. Avandia was in fact unsafe, and the use of Avandia posed an unreasonable risk of injury and death that outweighed the purported benefits of its use, such that injury was in fact caused to Decedent and others.

88. Defendant failed to adequately warn Decedent and those whom it knew Decedent would rely of the hazards associated with the use of Avandia and failed to provide this knowledge to Decedent and others. As a result of this failure to warn, Decedent was caused to suffer personal injuries and death.

89. Avandia was defective and unreasonably dangerous when it left the possession of Defendant in that, among other ways:

a. Avandia caused injury to the user far beyond any warned, noticed, expected or reasonable side effect or adverse reaction and when placed in the stream of commerce it contained unreasonably dangerous defects subjecting Decedent to risks from expected or known usage, including bodily injury and death, which exceeded the benefits of Avandia;

b. When placed in the stream of commerce Avandia was defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with diabetes;

c. Avandia contained insufficient and/or ineffective warnings to alert consumers and users to the risks of injury and death;

d. Avandia was insufficiently tested;

e. There were insufficient instructions on the proper use of Avandia; there were inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the significant risks previously described, Defendant failed to provide adequate warnings to users and consumers, and/or their physicians, and continued to promote the sale and use of Avandia;

f. Avandia had not been materially altered or modified prior to the use of said drugs by Decedent; and

g. Defendant was in the business of distributing and selling Avandia which form the basis of this lawsuit.

90. Defendant assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, supplied, packaged and/or sold Avandia in a defective condition that was unreasonably dangerous to the user or ultimate consumer of Avandia. Avandia was expected to and did reach the user, consumer, and Decedent without substantial change in the condition at which it was sold.

91. As a direct and proximate result of the defective condition of Avandia, Decedent sustained serious injuries and death.

92. Although Defendant knew or should have known that dangerous risks were associated with the use of Avandia, Defendant proceeded to or permitted the same to be advertised, promoted, distributed and sold without adequate warnings of the serious side effects and dangerous risks.

93. As a result, Decedent was personally injured resulting in his death. Plaintiff seeks damages including, but not limited to: medical expenses, physical and mental pain and suffering, lost wages, lost earning capacity, and any other relief to which the Court finds Plaintiff entitled.

94. The tortious actions and misdeeds of the Defendant as alleged herein are ongoing and at all times relevant hereto were ongoing and continuous and constituted ongoing and continuous torts. That said conduct herein described was intentional, fraudulent, reckless and malicious for which punitive damages are sought and should be awarded to deter the same or similar conduct in the future.

95. Due to the efforts of Defendant, sales of Avandia rose to more than three billion ($3,246,555,709.7600) dollars in 2006.[10]

96. Defendant's net income (adjusted earnings) in 2006 was approximately $10.6 billion.

97. As a result of Defendant's efforts and actions, the sale of Avandia became an enormous source of profits for Defendant.

98. Accordingly, Defendant had a significant financial incentive to suppress, misrepresent and/or conceal any potential dangers or risks associated with Avandia.

99. Plaintiff asserts that Defendant acted for the purpose of maximizing profits at the expense of the health of Decedent, and the health of others using Avandia. Plaintiff further asserts that Defendant had actual or constructive knowledge that Avandia posed a significant danger to anyone who used the drug, yet failed to take adequate or timely actions to prevent the injuries and deaths of users of Avandia or to warn the public of these dangers.

[10] http://www.gsk.com/investors/reps06/annual_review_2006/key_products.htm

100. Defendant failed to adequately or appropriately disclose material information relating to the dangers associated with Avandia. As a result, users of Avandia, including Decedent, were unaware of these dangers, did not have adequate information to know the warnings signs of being exposed to rosiglitazone and were therefore unable to avoid injury caused by using this defective drug product.

COUNT I
STRICT LIABILITY
DEFECTIVE DESIGN

101. Plaintiff re-alleges and reaffirms paragraphs 1-100 as if fully set forth herein.

102. At all times material hereto, the Defendant has engaged in the business of selling, distributing, supplying, designing, manufacturing, marketing and promoting the drug Avandia that is defective and unreasonably dangerous to consumers, including Decedent.

103. At all times material hereto, Avandia sold, distributed, supplied, designed, manufactured and/or promoted by the Defendant was expected to reach, and did reach, prescribing physicians and consumers in the State of Georgia, including Decedent, without substantial change in the condition in which Avandia was sold.

104. Avandia is a defective product in the sense that it is not reasonably safe for its intended use, based on an objective analysis weighing its risks and benefits against those of alternative anti-diabetic drugs, which were available throughout the time Avandia was on the market.

105. The design of the chemical formula for Avandia is defective.

106. At all times material hereto, the Avandia sold, distributed, supplied, designed, manufactured and/or promoted by the Defendant was in a defective and unreasonably dangerous condition at the time Avandia was manufactured, packaged, assembled, labeled, distributed,

supplied, and placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When manufactured, packaged, assembled, labeled, distributed, supplied, and placed in the stream of commerce, Avandia contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Decedent to risks which exceeded the benefits of the drugs;

b. When manufactured, packaged, assembled, labeled, distributed, supplied, and placed in the stream of commerce, Avandia was defective in design and formulation, making use of Avandia more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with diabetes;

c. Avandia was insufficiently tested;

d. Avandia was marketed to be used in a combination which was known to the Defendant to cause harmful side effects which outweighed any potential utility; and

e. Alone or in combination, Avandia was not safe for its intended use as anti-diabetic medication.

107. There was a serious risk of harm to the public that resulted from the defect in Avandia. Defendant was aware of the existence and seriousness of the defects prior to the injury of Decedent. Defendant did not correct the defects, or take other steps to reduce the danger of injury, until it was too late. The amount it would have cost to correct the defect, or reduce the danger, was small compared to the risk the defect posed to consumers and users of Avandia. The amount of profits that Defendant received from other sales of the defective drug was in the millions of dollars. Defendant attempted to conceal the defect or deceive the public about the safety of Avandia; and, Defendant has very significant financial resources.

108. But for the aforementioned defective and unreasonably dangerous conditions, Avandia would not have been prescribed to Decedent, Decedent would not have ingested Avandia, and Decedent would not have sustained the injuries alleged herein.

109. As a direct and legal result of the defective and unreasonably dangerous condition of Avandia, Decedent suffered cardiovascular injury and died.

WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT II
STRICT PRODUCT LIABILITY
FAILURE TO WARN

110. Plaintiff re-alleges and reaffirms paragraphs 1-109 as if fully set forth herein.

111. Avandia was defective and unreasonably dangerous when Avandia was manufactured, packaged, assembled, labeled, marketed, distributed, supplied, placed in the stream of commerce and when Avandia left the possession of the Defendant in that it contained warnings which were misleading regarding the purported benefits associated with Avandia and were inadequate and insufficient to alert physicians and consumers, such as Decedent, to the dangerous risks and reactions associated with Avandia, including, but not limited to, congestive heart failure, heart attack, heart injury, excessive fluid retention, fluid-overload disease and severe injury to the heart which could result in cardiac arrest and death and other serious and life threatening side effects. Decedent's injuries and losses are continuing in nature.

112. The physician prescribed Avandia to Decedent for its intended purposes, i.e., anti-diabetic agent.

113. The prescribing physician could not have discovered any defect in Avandia through the exercise of reasonable care.

114. The Defendant, as manufacture of prescription devices, is held to the level of knowledge of an expert in the field.

115. The prescribing physician did not have substantially the same knowledge as an adequate warning from the manufacturer or distributor should have communicated to the prescribing physician.

116. The warnings that were given by the Defendant to the prescribing physicians were not adequate, accurate, clear. and were ambiguous.

117. Defendant actively sought to "bury" the limited warnings provided in the fine print of the materials provided to the prescribing physician, and knowingly and intentionally failed to display those warnings prominently in order to hide from prescribing physicians and the consuming public the true risks of severe and life threatening complications which had been reported in association with Avandia, including but not limited to congestive heart failure, heart attack, heart injury, excessive fluid retention, fluid-overload disease and severe injury to the heart which could result in cardiac arrest and death.

118. The Defendant had a continuing duty to warn the prescribing physicians of the dangers associated with Avandia use.

119. Defendant's Avandia marketing, including direct-to-consumer advertising and promotions directed toward health care professionals, was a sustained campaign for more than seven years, characterized by misrepresentations by commission and omission as to the risks and benefits, particularly as to substantial increased risk of congestive heart failure, heart attack, heart injury, excessive fluid retention, fluid-overload disease and severe injury to the heart which could result in cardiac arrest and death suffered by Decedent associated with the ingestion of the drug.

120. The public, including Decedent, and prescribing physicians, including Decedent's prescribing physician, reasonably relied upon Defendant's misrepresentations as to Avandia's risks and benefits in deciding to take it and prescribe it.

121. As a direct and legal result of Defendant's failure to warn, Decedent suffered a cardiovascular injury and died.

WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT III
NEGLIGENCE

122. Plaintiff re-alleges and reaffirms paragraphs 1-121 as if fully set forth herein.

123. Defendant had a duty to exercise reasonable care in designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing and placing in the stream of commerce Avandia.

124. Defendant failed to exercise reasonable care in designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing and placing in the stream of commerce Avandia.

125. At all times material hereto, Defendant had a duty to Decedent to exercise reasonable care in the making, creation, manufacture, assembly, design, sterilization, testing, labeling, supplying, packaging, distribution, promotion, marketing, advertising, warning and/or sale of its respective drug products.

126. Defendant breached that duty and were negligent in its actions, misrepresentations, and omissions toward Decedent in ways which include, but are not limited to, the following:

a. Failure to include adequate warnings with the drugs that would alert physicians to the potential risks and serious side effects of the drugs;

b. Failure to adequately and properly test the drugs before placing the drugs on the market;

c. Failure to conduct sufficient testing on the drugs which, if properly performed, would have shown that the drugs had serious and dangerous side effects;

d. Failure to adequately warn Decedent's prescribing physician that use of the drugs should be accompanied by a professional examination and regularly scheduled follow-up examinations so that myocardial infarctions and other serious cardiovascular injuries could be avoided or detected early;

e. Failure to adequately warn Decedent's prescribing physician that use of the drug carried a risk of temporary or permanent disability due to myocardial infarction or death;

f. Failure to provide adequate post-marketing warnings or instructions after the Defendant knew or should have known of the significant risks of myocardial infarction and death from the use of Avandia;

g. Failure to adequately warn Decedent's prescribing physician that the drug products should not be prescribed for a long period of time;

h. Failure to warn Decedent's prescribing doctors that the drug product would not reduce diabetic complications and actually increase one's risk of myocardial infarction and death;

i. Failure to warn Decedent's prescribing doctors that the use of the drug products had not been studied as to safety in animals or humans;

j. Encouraging misuse and overuse while underplaying the side effects to doctors and the public in order to make a profit from sales;

k. Failure to properly manufacture, develop, assemble, prepare, design, sterilize, test, label, supply, package, distribute, promote, market, advertise, warn, and sell Avandia; and

l. Failure to conduct proper, adequate and appropriate pre- and post-marketing surveillance of drug reactions, adverse events, and safety signals, including failure to recognize clear product safety signals, as proper surveillance would have revealed.

127. Defendant knew, or should have known, that the defective condition of Avandia created an unreasonable risk of bodily harm to anyone using said products.

128. Despite the fact that Defendant knew, or should have known, that the defective condition of Avandia could cause serious and life threatening injuries to anyone who used Avandia, Defendant took inadequate steps to ensure that said products were safe, to notify consumers of this danger, to prevent said products from being used by persons such as Decedent.

129. Defendant knew, or should have known, that it was foreseeable that consumers, such as Decedent, would suffer injuries as a result of these Defendant's failures to exercise ordinary care.

130. The negligence of Defendant was a direct or contributing cause of the suffered by Decedent.

131. The negligent conduct of Defendant as set out in this Complaint was a direct and proximate cause of the severe injury to the heart and death suffered by Decedent.

132. There was a serious risk of harm to the public that resulted from the defect in Avandia. The Defendant was aware of the existence and seriousness of the defect. Defendant did not correct the defect, or take other steps to reduce the danger of injury, until it was too late.

133. The amount it would have cost to correct the defect, or reduce the danger, was small compared to the risk the defect posed to consumers and users of Avandia. The amount of profits that Defendant received from other sales of the defective drug was in the millions of dollars.

134. The Defendant attempted to conceal the defects or deceive the public about the safety of Avandia; and the Defendant has very significant financial resources.

135. But for the Defendant's negligent conduct as described herein, Decedent's prescribing physician would have never prescribed Avandia, Decedent would not have ingested Avandia, and Decedent would not have suffered harm from ingesting Avandia.

136. As a direct and legal result of the negligence of Defendant, Decedent suffered serious injuries.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages in an amount to be determined by a jury and demands trial by jury of all issues triable as of right by a jury.

COUNT IV
FRAUD AND MISREPRESENTATION

137. Plaintiff re-alleges and reaffirms paragraphs 1-136 as if fully set forth herein.

138. Defendant widely advertised and promoted Avandia as safe and effective medication.

139. Defendant had a duty to disclose material information about serious side effects to consumers such as Decedent.

140. Defendant had a duty to disclose all facts about the risks of use associated with Avandia, including the potential for the medication to cause congestive heart failure, heart attack, excessive fluid retention, fluid over-load, and possibility of severe injury to the heart which could lead to cardiac arrest and death.

141. Instead, Defendant touted Avandia as safe and effective treatment for type II diabetes without disclosing the true risks. Avandia was not as safe or as effective as Defendant represented.

142. Defendant intentionally failed to disclose this information for the purpose of inducing consumers, such as Decedent, to purchase Defendant's dangerous Avandia.

143. Had Decedent been warned or made aware of the dangers associated with Avandia, Decedent would not have consumed the product, which proximately led to Decedent's serious injuries described herein.

144. Defendant's advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations Defendant knew to be false, for the purpose of fraudulently inducing consumers, such a as Decedent, to purchase and consume Avandia.

145. Upon information and belief, Plaintiff avers that Defendant actively and fraudulently concealed information in Defendant's exclusive possession regarding the hazards associated with Avandia with the purpose of preventing consumers, such as Decedent, from discovering these hazards.

146. Any applicable statutes of limitation have been tolled by Defendant's knowing and active concealment and denial of the facts alleged herein. Decedent and other members of the public who were prescribed and ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Plaintiff's part, and could not reasonably have discovered the fraudulent nature of Defendant's conduct, and information and documents concerning the safety and efficacy of Avandia. Plaintiff may also rely on a tolling agreement with SMITHKLINE BEECHAM CORPORATION. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.

Wherefore, Plaintiff demands judgment for all damages available under law including but not limited to: past medical expenses, economic damages, costs, pre- and post-judgment interest, attorneys' fees, and any other relief available under the law.

COUNT V
BREACH OF IMPLIED WARRANTY

147. Plaintiff re-alleges and reaffirms paragraphs 1-146 as if fully set forth herein.

148. A warranty that a product is reasonably fit for its intended purpose is imposed by law on the seller of the product, including Defendant in the sale of Avandia.

149. Defendant breached this implied warranty, because Avandia is not reasonably fit for its intended purpose for the reasons explained above.

150. Decedent reasonably relied upon the belief that Avandia is reasonably safe for its intended purpose in making the decision to take the drug.

Wherefore, Plaintiff demands judgment for all damages available under law including but not limited to: past medical expenses, economic damages, costs, pre- and post-judgment interest, attorneys' fees, and any other relief available under the law.

COUNT VI
BREACH OF EXPRESS WARRANTY

151. Plaintiff re-alleges and reaffirms paragraphs 1-150 as if fully set forth herein.

152. Defendant created an express warranty that Avandia is reasonably safe for its intended purpose through the representations made to health care professionals and to the public, which were described above.

153. Defendant breached this express warranty, because Avandia is not reasonably safe for its intended purpose.

154. Decedent reasonably relied upon Defendant's express warranty in making the decision to take the drug.

155. Wherefore, Plaintiff demands judgment for all damages available under law including but not limited to: past medical expenses, economic damages, costs, pre- and post-judgment interest, attorneys' fees, and any other relief available under the law.

COUNT VII
VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW ("UTPCPL")

156. Plaintiff re-alleges and reaffirms paragraphs 1-155 as if fully set forth herein.

157. Defendant's actions are deceptive and in clear violation of UTPCPL, entitling Plaintiff to damages and relief under Pennsylvania Statute 73 P.S. § 201-1 *et seq.*

158. Plaintiff is a person within the meaning of UTPCPL, who was deceptively and unlawfully induced to purchase and/or use of Defendant's pharmaceutical drug Avandia.

159. Pennsylvania Statute 73 P.S. § 201-1 *et seq.* makes unfair or deceptive acts or practices in the conduct of any trade or commerce illegal.

160. Pennsylvania Statute 73 P.S. § 201-1 *et seq.* creates a private right of action for persons who are aggrieved by an unfair or deceptive act or practice by a supplier.

161. Pennsylvania Statute 73 P.S. § 201-1 *et seq.* provides that the prevailing party in litigation arising from a cause of action pursuant to Section 201-1 *et seq.* may be awarded costs and reasonable attorneys' fees within the limitations set forth therein from the non-prevailing party.

162. Pennsylvania Statute 73 P.S. § 201-1 *et seq* states that a corporation has violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law if the corporation "[r]epresent[s] that goods or services have . . . characteristics, ingredients, uses, benefits or quantities that they do not have[.]" The statute similarly provides that it is a violation if a

corporation "[e]ngage[s] in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding."

163. "Person" is defined under Pennsylvania Statute 73 P.S. § 201-1 *et seq* as "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities."

164. "Trade" and "commerce" is defined under Pennsylvania Statute 73 P.S. § 201-1 *et seq* as "the advertising, offering for sale, sale or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situate, and includes any trade or commerce directly or indirectly affecting the people of this Commonwealth."

165. Defendant is a person under Section 73 P.S. § 201-1 *et seq.* as it is incorporated under the laws of Pennsylvania and is authorized to do business in Pennsylvania.

166. Defendant has engaged in a trade or commerce under Section 73 P.S. § 201-1 *et seq.* as it has engaged in the practice of advertising, selling and distributing Avandia into the stream of commerce.

167. Plaintiff is a consumer within the meaning of Section 73 P.S. § 201-1 *et seq.*

168. As more fully described in this Complaint, Defendant's acts constitute unconscionable, deceptive, and unfair acts or practices in violation of Section 73 P.S. § 201-1 *et seq.*

169. Upon information and belief, Defendant continues to act deceptively in its manufacturing, marketing, distributing, selling and otherwise placing into the stream of commerce Avandia.

170. As a result of Defendant's unfair and deceptive trade practices, Decedent suffered economic loss and damage related to Decedent's purchase and use of Avandia.

171. As a result of Defendant's unfair trade practices, Plaintiff is entitled to an award of costs, reasonable attorneys' fees and treble damages pursuant to Pennsylvania Statute 73 P.S. § 201-1 *et seq.* if Plaintiff prevails.

WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried. The conduct, actions and inaction by Defendant as described herein were intentional, fraudulent, reckless and malicious for which punitive damages are sought and should be awarded to deter the same or similar conduct in the future.

COUNT VII
WRONGFUL DEATH

172. Plaintiff re-alleges and reaffirms paragraphs 1-171 as if fully set forth herein.

173. At all times material hereto, Defendant owed a duty to Decedent to protect him against reasonably foreseeable harms which a prudent person would anticipate were likely to result from Defendant's acts, omissions or neglect.

174. Defendant breached that duty when it acted in the negligent and/or tortious manner set forth herein.

175. The death of Decedent was directly and proximately caused by Defendant's wrongful acts, negligence and/or tortuous conduct alleged herein.

176. Defendant is liable to the Plaintiff as the surviving son of Decedent for the wrongful death of EDDIE JAMES WESTBROOKS, JR. because the injury that led to his death was caused by the Defendant or its agents' or servants' wrongful acts, neglect, carelessness, unskillfulness, and/or default.

177. As a direct, foreseeable and proximate result of Defendant's conduct, Plaintiff has incurred damages.

Wherefore, Plaintiff demands judgment against Defendant for damages in an amount to be determined by a jury and demands trial by jury of all issues triable as of right by a jury.

COUNT IX
PUNITIVE DAMAGES

178. Plaintiff re-alleges and reaffirms paragraphs 1-177 as if fully set forth herein.

179. At all times relevant hereto, Defendant GSK actually knew of the defective nature of Rosiglitazone as set forth herein and continued to design, manufacture, market, distribute and sell Rosiglitazone so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable serious harm caused by Rosiglitazone. Defendant GSK's deceptive conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, malice, recklessness, and/or willful and intentional disregard for the safety and rights of the Decedent, as well as the general public and/or consumers of Rosiglitazone. Plaintiff, therefore, are entitled to punitive damages for such conduct.

PRAYER FOR RELIEF

180. As a proximate, direct and legal result of Defendant's negligent, willful, wanton, malicious and/or oppressive behavior, Plaintiff seeks judgment and relief from Defendant including but not limited to the following:

A. Compensatory damages as allowed by law;

B. Punitive and exemplary damages as allowed by law;

C. Incidental and consequential damages as allowed by law;

D. Attorneys fees and costs as allowed by law;

E. Any other relief to which the Court finds Plaintiff entitled.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a Trial by Jury comprised of the maximum number of jurors allowed by law.

Respectfully submitted March 6, 2009.

R. Jason Richards, Esq.
Bryan F. Aylstock, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLLC
803 N. Palafox Street
Pensacola, FL 32501
Telephone: (850) 916-7450
Facsimile: (850) 916-7449
rjrichards@awkolaw.com
baylstock@awkolaw.com

Thomas Mellon, Esq.
Mellon, Webster & Shelly, PC
87 North Broad Street
Doylestown, PA 18901
Telephone: (215) 348-7700
Facsimile: (215) 348-0171
tmellon@mellonwebster.com

Attorney for Plaintiffs